

09/622206  
526 Rec'd PCT/PTO 14 AUG 2000

PATENT  
Attorney Docket No. 400683/SOEI

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

HISADA et al.

Filed: August 14, 2000

For: METHOD FOR  
QUANTITATIVELY DETECTING  
ANTIGEN

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**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form PTO-1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form PTO-1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ (a) within three months of the filing date of the patent application, (b) within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application, or (c) before the mailing date of a first Office Action on the merits.

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- ☐ **after** (a), (b), or (c) above, but before the mailing date of a final action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, and includes:
- ☐ the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below).
- ☐ the fee of \$240 set forth in 37 C.F.R. § 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a final action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, and includes the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below), a Petition requesting consideration of the Information Disclosure Statement (see "Petition" below), and the Petition Fee set forth in 37 C.F.R. § 1.17(i) (see "Fees" below).

### Copies Of The References

- ☒ Copies of the references listed on the enclosed Form PTO-1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 C.F.R. § 1.98(a)(3).
- ☐ A copy of the foreign search report is enclosed herewith.
- ☐ The references listed on the enclosed Form PTO-1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 C.F.R. § 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 U.S.C. § 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status ( <i>check one</i> )		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1. 0 /				
2. 0 /				
3. 0 /				

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### Other Applications

☐ The Examiner's attention is directed to the following U.S. patent application(s):

U.S. APPLICATIONS		Status ( <i>check one</i> )		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1. 0 /				
2. 0 /				
3. 0 /				

### Certification

- ☐ The **undersigned attorney** hereby certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned attorney** hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application or, to the knowledge of the attorney signing after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

### Petition

- ☐ The undersigned attorney hereby petitions the Commissioner to consider this Information Disclosure Statement and the references listed on the enclosed Form PTO-1449 in the examination of the above-identified patent application.

### Fees

- ☒ **No fee** is owed by the applicant(s).
- ☐ The **IDS Fee of \$240.00** under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The **Petition Fee of \$130.00** set forth in 37 C.F.R. § 1.17(i) is enclosed herewith.

### Method Of Payment Of Fees

- ☐ Attached is a check in the amount of \$ .
- ☐ Charge Deposit Account No. 12-1216 in the amount of \$ . (A duplicate copy of this communication is enclosed for that purpose.)

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**Authorization To Charge Additional Fees**

- ☐ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

**Instructions As To Overpayment**

- ☒ Credit Account No. 12-1216.  
☐ Refund

Respectfully submitted,

LEYDIG, VOIT & MAYER



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FORM PTO-1449  
MODIFIEDU.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.  
4000683/MARCONISERIAL NO.  
097622206  
UnassignedINFORMATION DISCLOSURE STATEMENT  
BY APPLICANTAPPLICANT  
HISADA et al.

(Use several sheets if necessary)

FILING DATE  
August 14, 2000GROUP  
Unassigned 1641

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO*
122	AA	WO 94/17409	08/04/94	PCT			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

122	AB	Bouman et al., "Microheterogeneity of Immunoglobulin G from Plasmocytomas", Z. Immun-Forsch. Bd. 150, S. 370-377 (1975).
	AC	Robinson et al., "Controlled Deamidation of Peptides and Proteins: An Experimental Hazard and a Possible Biological Timer", Proceedings of the National Academy of Sciences, Vol. 66, No. 3, July 1970, pp. 753-757.
	AD	Stott et al., "The Formation of Pyrrolid-2-one-5-carboxylic Acid at the N-Terminus of Immunoglobulin G Heavy Chain", Biochem. J., Vol. 128, (1972), pp. 1221-1227.
	AE	Cohenford, et al., "Nonenzymatic Glycosylation of Human IgG: In Vitro Preparation", Immunological Communications, Vol. 12, No. 2, 1983, pp. 189-200.
	AF	Pillai et al., "Myristoylation and the Post-Translation Acquisition of Hydrophobicity by the Membrane Immunoglobulin Heavy-Chain Polypeptide in B Lymphocytes", Proc. Natl. Acad. Sci. USA, Vol. 84, November 1987, pp. 7654-7658.
	AG	Shimura et al., "Affinity Probe Capillary Electrophoresis: Analysis of Recombinant Human Growth Hormone with a Fluorescent Labeled Antibody Fragment", Anal. Chem., Vol. 66, 1994, pp. 9-15.
	AH	"Set 5: Succinimidyl Esters and Carboxylic Acids", Molecular Probes, Inc., pp. 24-32.
	AI	Nishikawa et al., "Fluorescence Phosphorimetric Analysis", Kyoritsu Co., Ltd., Japan, 1989, pp. 1-3, English Translation.
122	AJ	"Monoclonal Antibodies", Chapter 6, pp. 139-243.
122	AK	"CODON Distribution in all Variable Region Heavy Chains" pp. 2143-2145.
122	AL	Hoogenboom et al., "Multi-subunit Proteins on the Surface of Filamentous Phage: Methodologies for Displaying Antibody (FAB) Heavy and Light Chains", Nucleic Acids Research, Vol. 19, No. 15, (1991), pp. 4133-4137.
122	AM	Kang et al., "Combinational Immunoglobulin Libraries in Phage λ", METHODS: A Companion to Methods in Enzymology, Vol. 2, No. 2, April 1991, pp. 111-118.
122	AN	"Site-directed Mutagenesis of Cloned DNA", Chapter 15, pp. 15.2-15.113.
122	AO	"Heavy Constant Chains CH1 Region" pp. 661-669.
122	AP	"In Vitro Amplification DNA by the Polymerase Chain Reaction", Applications for PCR Amplification, Chapter 14, pp. 14.5-14.35.
122	AQ	"Expression of Cloned Genes in Escherichia Coli", Production of Fusion Proteins, Chapter 17, pp. 17.3-17.42.
122	AR	"Detection and Analysis of Proteins Expressed from Cloned Genes", Production of Antibodies, Chapter 18, pp. 18.3-18.11.
122	AS	Japanese Language Reference, 3.7 through 3.7.3, pp. 160-165.

EXAMINER

DATE CONSIDERED

5/14/2004

\*A concise statement of relevance is being submitted in lieu of a translation. 37 CFR § 1.98(b).  
1449 (Rev. 3/8/2000)

+ Ref. not in English.